

REMARKS

Claims 1-3, 5, 6, 8-20, 22-28 and 30-34 are now pending in the application. Claims 24 and 26-34 are canceled by this amendment. New Claims 35-47 are added by this amendment. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

RESTRICTION REQUIREMENT

In the initial restriction requirement mailed August 8, 2006, the Office submitted that two inventions were claimed in the present application including an alignment device in claims 1-25 and a method of manufacturing an alignment device in claims 26-34. Applicants hereby cancel claims 26-34 to expedite prosecution of the present application. Nevertheless, Applicants maintain Applicants' objection to the Office's characterization of the claimed invention and submit that any process, such as blow molding or extrusion, can be a part of "forming." See Office Action mailed August 8, 2006.

As previously argued in the petition filed January 3, 2007, the term "forming", recited in independent Claim 26, did not exclude either blow molding or extrusion. Applicants wish to reiterate this interpretation of the claimed language in light of the decision on the petition mailed July 20, 2007. In the decision on petition, the Office noted that the positive recitations of Claim 26, including "attaching a spherical portion", are clearly not encompassed by blow molding or extrusion. Initially, Applicants respectfully submit that attaching a spherical portion to an end of longitudinal guide portion can indeed be performed by various processes, such as blow molding or

extrusion. Moreover, the decision on the petition does not describe how blow molding or extrusion excludes attaching a spherical portion to an end of a longitudinal guide portion. Applicants respectfully submit that the Office's interpretation of the claims is unduly narrow. The method elements recited in independent Claim 26 are not limited to a particular procedure, unless specifically identified. Therefore, recited elements including "forming", "attaching", "opening", and "coupling" do not require or limit the elements to a particular process or process step, but reasonably encompass all processes that could achieve the recited method.

Applicants have also cancelled all claims not relating to the species illustrated in Figs. 3A-3C in the accompanying text. Therefore, Applicants respectfully submit that all claims presently pending are directed to the elected group I and species 3. Applicants reserve the right, however, to file any unelected claims in a divisional application and submit that Applicants have the right to a reasonably broad interpretation of the claims in any divisional application.

CLAIMS OBJECTIONS

Claim 11 stands objected to because it recited "wherein the standoff features are located adjacent to the number of securing devices."

Applicants have deleted this language from Claim 11, and respectfully request that this objection be withdrawn.

REJECTION UNDER 35 U.S.C. § 103

Claims 1-3, 5, 6, 9, 11, 12 and 15-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over D'Urso (U.S. Pat. No. 5,752,962) in view of Mowlai-Ashtiani (U.S. Pat. No. 6,110,182). Claim 14 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over D'Urso in view of Mowlai-Ashtiani as applied to the claims above, and further in view of Ghajar et al. (U.S. Pat. No. 4,998,938). Claims 22, 23 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over D'Urso in view of Mowlai-Ashtiani, and further in view of Hennig (U.S. Pat. No. 6,328,748). These rejections are respectfully traversed.

Prior Art

Applicants note that D'Urso is directed to a method of using stereotactic head frames that include large ring apparatuses (Fig. 1), large tripods (Fig. 3), a small tripod (Fig. 4), and a small adhesion system (Fig. 5). Regarding the small tripod, three legs 21 extend from a socket 25. Each leg has a foot 22 through which a screw (unnumbered) engages a region of the anatomy 24. A locking screw 30 engages the spherical instrument support 26 through the socket 25. D'Urso does not describe deforming any portion of the assembly, as submitted in the Office Action. See Office Action mailed August 6, 2007, paragraph 1. In fact, D'Urso only states "a locking screw 30 is mounted in socket 25 to lock the support member 26 in a predetermined position." See D'Urso, col. 6, lines 20-21.

Mowlai-Ashtiani is directed to a target socket 10 that is positioned on a ring 80 relative to a patient 76. The socket includes a ring 12 that defines an innerband 16 that

can engage a target ball 32. The ring further includes partial channels 22, 24 that extend only partly through the ring in order to maintain integrity of the ring so that the ring can flex. Certain wall portions 26, 28, however, will not permanently deform. See Mowlai-Ashtiani, col. 3, lines 39-44. A tightening member 52 is provided to move the ring.

Hennig is directed to a system that includes a lower ring 1 with a threaded section 8 that directly engages an opening in a skull. See Hennig, col. 5, line 26-30. The lower ring includes a second set of threads 9 that are engaged by a set of threads on a second ring 3. The ball 2 is held in place by threading the second ring onto the first ring and engaging the ball with both the second ring and the first ring, each having curved surfaces 21, 22 to engage the ball. See Hennig, col. 5, line 67 to col. 6, line 11.

Finally, Ghajar et al. is directed to a skull mounted work platform that directs an instrument to enter a brain at 90 degrees to a plane tangent to the brain. See Ghajar et al. col. 2, Ins. 58-65 and Fig. 5. Ghajar et al. fails to disclose at least a spherical socket.

Claim 1

Initially, Applicants respectfully submit that D'Urso and Mowlai-Ashtiani are not properly combined. Applicants submit that there is no articulated specific reason in the Office Action for combining D'Urso and Mowlai-Ashtiani. Moreover, Mowlai-Ashtiani can not be combined with D'Urso because the combination would be inoperable and is contrary to the teachings of each of the references. Assuming that the socket 25 of D'Urso is replaced with the ring 10 of Mowlai-Ashtiani, then the legs 21 of D'Urso would not allow the ring to compress using the channels 22, 24 of Mowlai-Ashtiani. The legs

21 are rigidly held to the anatomy 24, as illustrated in D'Urso Fig. 4, thus the socket 25 can not move relative to the anatomy 24 to allow it to compress and hold the spherical instrument support 26. Therefore, a combination of D'Urso and Mowlai-Ashtiani would defeat the purpose of both of the devices and appears to be improper. Because of the legs of D'Urso, the ring of Mowlai-Ashtiani could not compress to hold the ball.

Applicants respectfully submit that at least one element from Claim 1 is completely missing from both D'Urso and Mowlai-Ashtiani, therefore, a prima facie case of obviousness can not exist regarding independent Claim 1. For example, amended independent Claim 1 recites "an actuating device surrounding and engaging an outer perimeter of the spherical socket, wherein the actuating device is not in direct contact with the spherical portion." As discussed above, D'Urso discloses that a locking screw locks the spherical instrument support relative to the socket. This is clearly illustrated in Fig. 4 where the locking screw 30 appears to include only a single shaft that somehow engages the socket 25. Regardless, neither Fig. 4 nor the description in D'Urso describe an actuating device surrounding and engaging an outer perimeter of the spherical socket. Moreover, an actuating device that is not in direct contact with the spherical portion appears to be contrary to the disclosure of D'Urso. D'Urso appears to disclose the locking screw (the only portion that may reasonably be interpreted as the claimed actuating device) directly contacting the support member to lock the support member in the predetermined position.

Mowlai-Ashtiani also fails to disclose or render obvious at least this element of independent Claim 1. As discussed above, the ring is compressed with the screw 52. Mowlai-Ashtiani further describes that a cutout region 50 is provided to accommodate

the screw. See Mowlai-Ashtiani, col. 3, lines 62-63. As illustrated in Figs. 2 and 3 of Mowlai-Ashtiani, an actuating device does not surround and engage an outer perimeter of the ring, therefore, Mowlai-Ashtiani also fails to disclose at least this element. Because D'Urso and Mowlai-Ashtiani fail to disclose at least one element of independent Claim 1, neither reference, either alone or in combination, can render obvious independent Claim 1.

Therefore, Applicants respectfully submit, that independent Claim 1 is in condition for allowance at least because a prima facie case of obviousness does not exist. At least one element in independent Claim 1 is missing from both D'Urso and Mowlai-Ashtiani and/or the combination of D'Urso and Mowlai-Ashtiani is not proper.

Applicants also submit that each of the claims that depend from Claim 1 should be in condition for allowance.

Claim 11

As discussed above, Applicants respectfully submit that the combination of D'Urso and Mowlai-Ashtiani is improper at least because such a combination would render the resulting device inoperable.

Moreover, assuming the combination is proper a prima facie case of obviousness can not be made because the combination still fails to disclose or render obvious at least one element of Claim 11. Amended independent Claim 11 recites "at least one relief opening in a portion of the spherical socket defined by a complete disassociation of at least two portions of the spherical socket, allowing deflation of the spherical socket." Initially, Applicants note that neither D'Urso (which discloses a socket 25 and a

locking screw 30), nor Mowlai-Ashtiani (which discloses channels 22, 24 that terminate at walls 26, 28) disclose a relief opening defined by a complete disassociation of at least two portions of the spherical socket. Therefore, Applicants respectfully submit that at least a prima facie case of obviousness does not exist in light of D'Urso and Mowlai-Ashtiani.

Therefore, Applicants respectfully submit that independent Claim 11 is in condition for allowance in light of D'Urso and Mowlai-Ashtiani, as are each of the claims that depend from Claim 11.

Regarding Claim 14, Applicants submit that Ghajar et al. does not overcome the failings of D'Urso and Mowlai-Ashtiani, either alone or in combination, therefore Claim 14 should also be in condition for allowance.

Claim 17

Amended independent Claim 17 recites "at least one standoff feature having a standoff feature thickness . . . an attaching device . . . wherein the at least one standoff feature defines a passage through which the attaching device is operable to pass substantially freely; and a retention force providing member coupled to the base unit and operable to retain the attaching device near the passage." The Office Action simply notes that a screw retention feature is the internal thread of the apertures 23 in D'Urso. See Office Action, August 6, 2007, page 3, paragraph 1, and lines 9-10. Applicants respectfully submit that D'Urso, however, does not disclose internal threading of apertures 23. D'Urso only discloses "the feet 22 having mounting apparatuses therein for attachment to a region of anatomical pathology 24." See D'Urso, col. 6, lines 12-13.

Applicants respectfully submit that Fig. 4 does not further clarify or expand upon this description as the portion that is illustrated extending between the feet 22 and the anatomy 24 is not numbered or further described. Therefore, Applicants respectfully submit that the Office's characterization of D'Urso is unsupported by the disclosure of D'Urso. Moreover, Applicants respectfully submit that the feet 22 are resting adjacent and contacting the anatomy 24 and do not actually provide any standoff feature thickness. Finally, D'Urso does not disclose or illustrate a passage through which the attaching device is operable to pass substantially freely. Even assuming that there is an internal thread in the aperture 23, a screw could not then pass freely through it. Therefore, Applicants respectfully submit that D'Urso does not anticipate or render obvious independent Claim 17 because D'Urso fails to disclose any passage or retention force providing member. Applicants also submit that such a disclosure is not found in Mowlai-Ashtiani. Even the Office appears to find the same failing of Mowlai-Ashtiani as no indication is provided in the Office Action of such a disclosure Mowlai-Ashtiani. Therefore, Applicants respectfully submit that there is no prima facie case of obviousness to be made in light of D'Urso or Mowlai-Ashtiani, either alone or in combination, to reject independent Claim 17. Further, Applicants respectfully submit that the combination of D'Urso and Mowlai-Ashtiani is improper, as discussed above.

Therefore, independent Claim 17, and each of the claims that depend directly or indirectly therefrom, are in condition for allowance.

Applicants also respectfully submit that claims that depend from independent Claim 17 include patentable subject matter. For example, Claim 18 recites "the retention force providing member includes an elastomer band" and Claim 20 recites "the

retention force providing member is located external to, and above the passage." Applicants respectfully submit that neither D'Urso nor Mowlai-Ashtiani disclose these elements.

Claim 22

Claim 22 is rejected under the combination of D'Urso, Mowlai-Ashtiani, and Hennig . Applicants respectfully submit that the combination of each of the three references is improper. As discussed above, the combination of D'Urso and Mowlai-Ashtiani is improper because such a combination would render the device inoperable. Further, Hennig disparages any device where a ball center point is located outside of the area defined by the cranium. See Hennig, col. 1, lines 41-45. Hennig's device is described where a lower ring has an external thread for direct screwing into an area of the patient's skull. See Hennig, col. 2, lines 33-35. This is reiterated in the detailed description of Hennig in that the lower ring's lower threaded surface is screwed into the wall of the formed burr hole. See Hennig, col. 5, lines 62-63. Contrary to Hennig, both D'Urso and Mowlai-Ashtiani include ball portions that are positioned away from the cranium. As described and illustrated in D'Urso, the spherical instrument support 26 is held within a socket that is held off the anatomy 24 with legs 21. Mowlai-Ashtiani discloses the ring 12 interconnected with a ring 80 that is also displaced from the patient 76. Therefore, Hennig specifically disparages and teaches away from the devices as illustrated in D'Urso and Mowlai-Ashtiani. Accordingly, Applicants respectfully submit that Hennig can not be combined with D'Urso and Mowlai-Ashtiani.

Independent Claim 22 recites “a longitudinal guide portion . . . an insert located substantially within the longitudinal opening wherein an outer diameter of the insert fits closely with a longitudinal opening, and an inner diameter is sized to fit closely with a device to be guided.” Applicants also submit that at least one element of Claim 22 is missing from each of the references, either alone or in combination. Applicants note that the Office Action concedes that neither D'Urso nor Mowlai-Ashtiani disclose an insert. See Office Action mailed August 6, 2007 page 6, line 17. Further, Applicants respectfully submit that the adapter 17 of Hennig can not reasonably be interpreted as the insert recited in Claim 22. The adapter 17 is not disclosed to be located substantially within the longitudinal opening or that an outer diameter fits closely with a longitudinal opening of a longitudinal guide portion. Although Hennig discloses that the “adapter 17 which is specifically adapted to the equipment which is to be passed down the tube” it does not reasonably follow that an inner diameter of the adapter 17 is sized to fit closely with a device to be guided. Therefore, Applicants respectfully submit that a prima facie case of obviousness has not been made, either alone or in the combination of D'Urso, Mowlai-Ashtiani, or Hennig.

Therefore, independent Claim 22 and each of the claims that depend directly or indirectly therefrom are in condition for allowance.

NEW CLAIMS

New Claims 35-47 are added by this amendment. Applicants respectfully submit that each of the newly added claims are within the scope of the previous election and no new subject matter is added.

Moreover, Applicants submit that each of the new claims include patentable subject matter. For example, dependent Claim 37 recites “wherein the actuating device engages an entire perimeter of the spherical socket.” Dependent Claim 38 recites “wherein the relief openings are defined as a complete passage between at least two members defining the spherical socket.” Dependent Claim 40 recites, “the base unit further includes a substantially planar portion wherein the spherical socket extends from a first side of the substantially planar portion and the number of standoff features attached to the base unit extend from a second side of the substantially planar portion; wherein the spherical socket includes at least two members hingedly connected to the first side of the substantially planar portion.” Dependent Claim 42 recites “wherein the base unit further includes a substantial planar portion wherein the spherical socket extends from a first side of the substantially planar portion and the number of standoff features attached to the base unit extend from a second side of the substantially planar portion.” Applicants respectfully submit that the elements as recited in the dependent claims, such as those referenced above, include patentable subject matter in light of D'Urso, Mowlai-Ashtiani, Hennig either alone or in combination.

Moreover, new independent Claim 43 is also in condition for allowance in light of these references. As discussed above and recited in independent Claim 43, Applicants respectfully submit that it is not rendered obvious that a deformable socket includes at least two fingers extending from a first portion and a complete separation between the at least two fingers. Moreover, independent Claim 43 recites “an actuating device that surrounds and engages the entire perimeter of the spherical socket.” Further, independent Claim 43 recites “a retaining force applying member operable to hold the

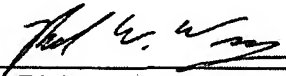
attaching device relative to the passage." In addition, the claims that depend from independent Claim 43 also include patentable subject matter. Therefore, Applicants submit that each of the newly added claims is in condition for allowance.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

Dated: Oct. 23, 2007

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